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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,711	09/11/2003	Carl R. Merril	NIH298.1DC1CC1	4758

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EXAMINER	
SNYDER, STUART	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,711	MERRIL ET AL.	
	Examiner	Art Unit	
	Stuart W. Snyder	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20 and 22-26* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20,22 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 18, 2006 has been entered. Claim 23 is rejoined to the other elected claims because prior art is not found for the elected species; claims 20 and 22-26 are pending.

Claim Objections

Claims 24-26 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 24-26 depend on claim 20 that is drawn to a method of producing a bacteriophage; however, claims 24-26 are drawn to methods of administering the bacteriophage that is not germane to the subject matter of claim 20.

Claim Rejections - 35 USC § 112, 1st Paragraph—Enablement

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 20, 22 and 24-26 were previously rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement; because of the rejoinder of claim 23, claims 20 and 22-26 stand rejected

under 35 USC 112, first paragraph as failing to comply with the enablement requirement.

In response to this rejection, Applicant has filed an affidavit outlining specific steps involved in constructing a complement evading bacteriophage and which were available to the skilled artisan at time of filing. The outline includes a recitation of adding the hexapeptide to one of the coat proteins of lambda phage and cites a review article in favor of the particular peptide, LARSNL, which contains the C3 convertase scissile bond of C3.The specification and Applicant's arguments are a discussion of microbiological and molecular biological techniques and how they might be applied. There is a specific teaching as to how to apply them to the matter at hand; e.g., extending phage resistance to host immune system by mutating the surface coat protein with the addition of a specific amino acid sequence to its C-terminus. There is no dispute that methods of genetic engineering were well known but in sharp contrast to another method outlined in the instant specification, e.g., the method of obtaining phages which delay inactivation by HDS using serial passages of the phage in mice, there is no teaching the specification nor in subsequent non-patent literature that the claimed genetic engineering method was ever attempted or if attempted was ever successful in producing phages that are capable of evading a HDS for scientific reasons as described below.

The potency of the specified peptide (LARSNL) in inhibiting C3 convertase, the classic and alternative complement pathways is a matter of scientific dispute. Whereas Schasteen et al. demonstrate modest inhibition by the peptide in complement activation

inhibition assays (IC_{50} ~500 μM, see Table 1, p 1271), Peake et al. found approximately 10-fold higher IC_{50} when using this peptide in assays which directly measured the enzymatic hydrolysis of C3 (IC_{50} ~5 mM, see table 2, p 456). Schasteen et al. further teaches that the context of the inhibitory peptide is important (see esp. Tables 2 and 3, p 1272); for example, in Table 2, peptide 1 has little or no intrinsic inhibitory activity whereas an analogue has complete inhibitory activity of both complement pathways when presented in the context of a "short core" construct. This conclusion is underscored by the data presented in Peake, et al. in that a peptide of the amino acid sequence RSNL had 10 times the inhibitory activity as did LARSNL in the same enzymatic assay. Thus, it would be difficult if not impossible to predict a priori if the proposed lambda phage construct would have complement activation inhibitory activity in view of the scientific controversy surrounding the efficacy of short inhibitory peptides and their immediate context. Additional considerations of steric hindrance by the lambda phage coat protein for access of complement convertases to the putative inhibitory peptides are not addresses by applicant; it may be necessary for linkers to be inserted between the C-terminus of the phage coat protein and proposed inhibitory peptides. Therefore, rejection of claims 20 and 22-26 are maintained under 35 U.S.C. 112, 1st paragraph.

Claim Rejections - 35 USC § 112, 2nd Paragraph—Lack Antecedent Basis

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

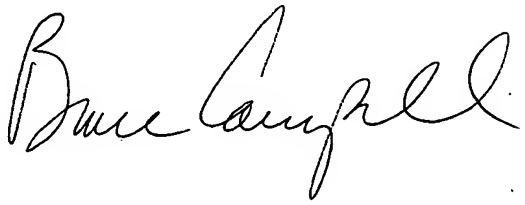
Claims 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 recites the limitation "bacteria" in reference to claim 20; claim 23 depends on claim 22 and further limits mycobacteria to one of three distinct species. There is insufficient antecedent basis for these limitations in the claims. Claim 20 is drawn to a method of producing bacteriophage. The specification teaches manipulation of bacteriophage genome followed by infection of host bacteria as part of the method for producing said bacteriophage. The specification also teaches that said bacteriophage is intended for treatment of bacterial infections in animals, however the use is not specifically claimed nor is any recitation of "bacteria" found in claim 20.

Claims 24-26 recites "method of claim 20, wherein the bacteriophage is administered". Claim 20 is drawn to a method of producing bacteriophage. Neither the specification nor literature cited by the Applicant teaches the administration of the bacteriophage as part of the method for producing the bacteriophage. Rather, the specification and cited literature teach molecular biological techniques and strategies that are limited to manipulation of the bacteriophage genome and its propagation in prokaryotic hosts. Therefore, claims 22-26 are properly rejected under 35 U.S.C. 112, 2nd paragraph because each lacks antecedent basis in claim 20.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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